

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO:
ALL CLASS ACTIONS

CIVIL ACTION: 01-CV-12257-PBS
Judge Patti B. Saris

DECLARATION OF CHARLES M. ALCORN

1. My name is Charles M. Alcorn and I reside at 1405 Alsace Road, Reading, PA 19604.
2. I am currently in my final year of law school at Temple Law School.
3. I was an employee of the Schering-Plough Corporation (SP) from January 1997 through June 2002. Prior to working for SP, I worked at Aetna as a Vice President in health analysis and statistics. I have also directed health care statistical analysis groups for US Healthcare, Prudential Insurance, and the Medicare and Medicaid review agent for New York State.
4. The facts testified to in this affidavit are based upon my personal knowledge acquired in the regular course of business in my employment with SP, in my position as Director of ITG Development Operations of ITG, and in the position of a whistleblower assisting the Department of Justice in its investigation and prosecution of a False Claim Act and Kickback violations by SP.

5. While employed by SP, I and more than 100 other SP employees were assigned to work for the disease management unit of SP, a wholly-owned subsidiary named Integrated Therapeutics Group (ITG).

6. My position at ITG was the Director of ITG Development Operations as shown by chart number 06.12 at SW0638455 of Exhibit 407. As Director of ITG Development Operations I regularly participated in staff meetings and discussions with SP officers and employees regarding SP's managed care business operations, marketing and contracting. I also had discussions with individual or small groups of SP management on the use of reimbursement spreads of SP products based on inflated AWP's as a marketing tool. Also, as Director of ITG Development Operations I routinely had access to and reviewed SP memoranda and documents produced and kept in the regular course of business regarding the operations, marketing and contracting for SP drugs, including SP's line of albuterol inhalants and solution, with managed care customers such as IPAs, HMOs and PBMs.

7. ITG's offices were located in SP's headquarters in Kenilworth, New Jersey, approximately fifty feet from the offices of Raul Cesan, President and COO of SP. ITG operations were financed by SP entirely. ITG was totally operated and controlled by SP officers and employees. Over the course of ITG's history, the SP officers who directed and controlled ITG were Raul Cesan, Richard Zahn, Len Camarda, Bruce Wallace, Gary Binder, Linda Zhou, and Roch Doliveux. Corporate Schering-Plough in-house counsel were responsible for creating and executing ITG's health management contracts with its managed care customers.

8. Within one year of my employment, I along with two other whistleblowers (Beatrice Manning and Ray Pironti) identified SP's fraudulent practices involving inflated best prices for their pharmaceutical products, met with Jim Sheehan from the Eastern District of

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Fed. R. Evid. 402, 403
See Memorandum, Part I

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Fed. R. Evid. 404(b)
See Memorandum, Part II

Pennsylvania US Attorneys Office, and filed a sealed complaint as a co-plaintiff with the US government under the qui tam provisions. During the next four years of my employment with SP, I cooperated with the US Attorneys Office investigation of SP's illegal marketing practices that resulted in a global resolution during the summer of 2004 with the United States Attorney for the Eastern District of Pennsylvania that included the following components: (1) SP's wholly-owned subsidiary, Schering Sales Corp., pled guilty to a violation of the Anti-Kickback Statute for paying a kickback to two customers in exchange for preferred formulary treatment of Claritin and SP paid the fine of \$52.5 million assessed for the criminal violation; (2) SP agreed to settle its False Claims Act liability and to pay to the United States, 50 Medicaid programs, and certain Public Health Service entities \$292,969,482 for Schering's failure to report its true best price for Claritin; and (3) SP entered into a Corporate Integrity Agreement with DHHS to correct its government pricing reporting failures.

9. As part of the criminal plea agreement with SP and the Eastern District of Pennsylvania US Attorneys Office, Schering Sales Corporation rather than Schering-Plough or ITG was named as the defendant. At the time of settlement with US Attorneys Office, ITG no longer existed as Schering-Plough had shut it down over a several year period when it became apparent that they could no longer continue the illegal kick back practices. SP was slow to exit these practices as many of the existing managed care contracts that resulted in the corporation's huge profits were dependent upon them. Schering Sales Corporation, like ITG, was indistinguishable from Schering-Plough Corporation (same offices, same paychecks, same management), was identified by the US Attorneys Office to take the plea so that Schering-Plough Corporation could continue to market its drugs to federal and state programs. At the time of the settlement with US Attorneys Office for the Eastern District of Pennsylvania, Schering-

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Plough no longer employed former senior management primarily responsible for the illegal practices. The new CEO of the company had committed to discontinue such past illegal practices.

10. SP had used an intricate scheme that involved many of its subsidiaries, including ITG, Schering Corporation and Warrick, to cheat Medicaid out of hundreds of millions, if not billions, of dollars. SP evaded its responsibility to charge the U.S. government and its beneficiaries the lowest price it charged to the private sector, i.e., the best price required by federal law. Most of the scheme was carried out using ITG. The scheme, which centered on SP's blockbuster drug Claritin, had three major elements that served as "kick-backs" and hidden rebates and/or discounts.

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Fed. R. Evid. 404(b)
See Memorandum, Part II

11. The first element: ITG provided free or well-below-cost health management services to HMOs that put Claritin on formulary. The value of these services were not included in the best-price calculation SP used to establish Medicaid pricing. ITG would sign a contract with the HMOs and this contract would be ostensibly totally separate from the rebate contracts that SP would sign with the managed care organizations. Medicaid auditors would review the rebate contracts with SP (not ITG) and thus would never see the additional "kick-backs" or hidden rebates/discounts SP gave through ITG. The role of ITG services are reflected in Exhibit 565, a draft memo from Linda Zhou, who was then the head of SP's Contracts and Pricing division. In this memo, Zhou is making the "business case" for further investment into ITG's computer capacity. On page 2, under Roman numeral I, Zhou states, "ITG's services complement and enhance Schering's pharmaceutical products and meaningfully differentiate them from the competition. Thus, they provide our primary means of implementing the strategy to compete on a basis other than price." On the next page under the section of "Increased

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Profitability” Zhou stated, “By allowing us to compete on a basis other than price, ITG has increased Schering Lab’s profitability. Total discounts as a % of contracted gross sales has declined in 1996 from 23% in 1996 to 17% currently. At 1998 LE sales levels, this equates to annual savings of \$222 million.”

12. The second element: ITG also made money payments (kick-backs) or gave unreported free goods, including Warrick inhalants, to major PBMs and HMOs. The money payments were disguised for reporting purposes as “administrative fees” “partnership fees” or “data fees.” This occurred during the years that I was working at SP from 1997 through 2002. I have personal knowledge of the use of such free goods because in my management position, I was required to attend operations meetings that included a review of managed care contracts (normally provided by Linda Zhou or Carolyn Kocis who reported to her) including the value given to managed care organizations to obtain their business. The use or value of free goods would not be reflected in as discounts for price reporting or reflected in AWP’s for the drugs involved.

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Fed. R. Evid. 402, 403
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13. The third element: SP, through ITG, “gave” the managed care organizations nominally priced drugs. “Nominal Prices” are steeply discounted drugs priced at 90% or more off of AMP. The value of nominally priced drugs to MCOs as a contract tool is premised on the fact that the MCO has a dispensing arm (pharmacy) and would sell the drug at full price or would be reimbursed as if acquired at regular direct price by third party payors using AWP-based reimbursement factors, such as Medicare, plus any co-pays from the individual program beneficiary. The nominal pricing strategy employed by SP is set forth in Exhibit 714. Although I was not present or employed by SP at the time Exhibit 714 was created, the author of Exhibit 714, Carolyn Kocis, was a fellow SP executive with me in ITG for the period of time when I was

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Fed. R. Evid. 402, 403
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Fed. R. Evid. 602
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employed by SP. Kocis's position in ITG was Senior ITG Customer Manager. However, during my employment at SP, I witnessed first hand that Kocis, together with Linda Zhou, Len Camarda and Roch Doliveaux implemented the nominal pricing strategy described in Exhibit 714 in marketing SP drugs in the managed care market.

14. As an integral part of the strategy to *compete on a basis other than price*, SP relied on the value of spreads created by highly inflated AWP's for drugs, including Proventil and Warrick albuterol inhalers and solution that were reimbursable by Medicaid, Medicare and third party payors. These drugs were "given" as nominally priced drugs in connection with the scheme to avoid Medicaid rebates and equalize pricing of Claritin in managed care contracts. SP did not account for the value of the hidden rebates/discount given from the nominally priced Warrick inhalants and solution in SP sales or rebate/discount records. Essentially, SP was keeping two sets of accounting books, one for SP, one for ITG. SP hid the value of the ITG services, money payments/free goods and nominally priced Proventil and Warrick inhalants and solution in ITG's books.

15. I have reviewed Exhibit 497 authored by Brian Longstreet. The comments in said exhibit regarding creating favorable reimbursements spreads through manipulations of AWP and sales pricing for both branded and generic products reflect a well-known and well-accepted marketing practice for the sale of SP products; however, it was unwritten SP policy for SP employees not to admit to such practices outside the corridors of SP offices or personnel.

16. As Director of ITG Development Operations, I would often witness marketing preparations and presentations to managed care organizations including their medical, pharmacy, contracting, and financial department directors. It was a routine marketing practice and presentation for field forces to market the reimbursement spreads created by false AWP's, such as

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Fed. R. Evid. 602
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the AWP of Proventil and Warrick inhalants and solution, to show the value of the nominally priced drugs being "given" as part of a managed care contract. Normally, all of the "benefits" of the ITG contract or giveaways would be listed in a power point presentation to these managed care customer directors. The fact that these giveaways would result in a new lower best price for Schering's various pharmaceutical products was not discussed with SP's managed care customer's staff openly. Rather, the quid and the quo in the quid pro quo scheme was understood among the parties in a sort of "wink wink - it works for both of us, so lets do it."

17. In preparation for these presentations and the formulation of the ITG contract with the managed care customer, SP and ITG field forces routinely created spreadsheets showing the comparative reimbursement spread values created by false and highly inflated AWP's of SP drugs, including Warrick albuterol inhalants and solution, compared to competitor drugs. To my knowledge, all of these spreadsheets, at the direction of SP Corporate in-house counsel, were destroyed by the field force once the necessary quid and combination of giveaways was determined. I know about the destruction of these spreadsheets (or worksheets to calculate the giveaways and false AWP) because Kathy Hasty from the field staff shared one with me that she had developed for one of her customer ITG contracts. The reason for giving me a copy was because she needed input from me on the costs of data processing and the associated health management services for the customer. She indicated that I should destroy the spreadsheet after my review as Schering legal had told her to do so.

18. During my five years of employment at Schering-Plough, senior management never indicated that SP in-house lawyers, who had full knowledge of the illegal and deceptive practices, advised us at any time not to pursue the schemes outlined above because said marketing practices were illegal. To the contrary, the SP in-house lawyers, including Joe Larosa

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and the lawyers who reported to him, were instructed by Senior Vice President Roch Doliveux, that a specific business strategy, such as the competing-on-a-basis-other-than-price and nominal pricing strategies, would be pursued and that SP lawyers would assist in developing and implementing a contracting strategy. SP senior executive Roch Doliveux required that ITG's services and payments for data had an ITG-specific contract developed by SP in-house counsel associated with them. Normally, the contracts had language in them requiring exclusive or preferential treatment of Claritin on the prescription formulary. Under the quid pro quo, the MCO or PBM got the services and/or payments and/or nominally priced drugs in exchange for selection of Claritin as a preferred drug or inclusion on the formulary. If the kickback was not sufficiently large, the MCO or PBM would threaten to remove Claritin from the formulary. The contracts articulated the health management services to be provided as well as the data management fees to be paid by Schering. I do not recall specific mention or language in the contracts of the nominally price drug give aways. Rather, these arrangements were agreed to and tracked in a separate spreadsheet maintained by Linda Zhou along with other free or underpriced services and payments to specific MCOs or PBMs. As Head of ITG Development, I was asked to supply information on the value of services provided along with budget cost data for development and data processing fees. Linda Zhou, then Head of Contracting and Financing for Schering Plough, reported to me that the purpose of this approach was to establish facial legitimacy, prevent detection by government auditors, and minimize liability --- conversation with Linda Zhou, then Head of Finance and Contracting for Schering Plough in connection with Eastern District for Pennsylvania US Attorneys Office investigation. In the same conversation, and much to the interest of the FBI agents from the Philadelphia Office assigned to our case, she noted that the company would owe millions of dollars if detected by government auditors and

that she took her computer home everyday to prevent such detection. In the case of the Claritin best price scheme, two contracts were developed for each managed care customer ---- one contract that reported the actual cash rebate subject to Medicaid audit in determination of best price and another contract maintained separately that detailed the various hidden rebates. All of the illegal and/or deceptive marketing practices described herein were planned and implemented with the full participation of SP in-house counsel.

19. Functionally, SP's in-house counsel reported to the business unit heads organized by pharmaceutical product line (such as oncology, allergy, cardiac divisions) and their success and compensation was dependent upon their level of cooperation with the sales side of the organization. SP's practice was to hire young, debt-ridden lawyers fresh out of law school. Those who cooperated with the business units illegal schemes were promoted with higher compensation and increased responsibility while those who questioned the legality of the business unit practices were "reassigned" to administrative tasks or terminated for poor performance. If an in-house lawyer or any other staff person questioned the legality of a specific business practice, they were labeled as someone who obstructed sales and the success of the company. On several occasions, I declined to certify that the value of data received from a customer was worth what we paid for it. I was told by Gary Binder, my supervisor at the time, that I was obstructing the success of the company if I did not sign off on the value. He said that I could end up like one of the lawyers who refused to sign-off on ITG's business contracts. Specifically, "although she was African American and a Harvard graduate, she was terminated from the company because she could not get any work done because she thought all the contracts had legal problems." I also worked with another lawyer later whose name I recall as Randy

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Nixon who told me he was reassigned to perform administrative tasks after he questioned the legality of a contract.

20. Sales (as did corporate income and incentive payments to sales staff) of Schering's earlier (it was my understanding that clinicians thought of this earlier version as archaic compared to the newer improved version to be introduced by Schering) hepatitis C therapy, such as Intron-A, had plunged while doctors awaited the promised arrival of a new improved therapy from the company. The release of the new therapy was delayed by the Food and Drug Administration because of the company's manufacturing problems. Roch Doliveux was the primary architect of the larger concept that Schering should re-direct corporate monies paid to qualified organizations completing clinical trials to managed care organizations and prescribing doctors instead in order to increase product sales. His view was: "Why should we pay money to clinical researchers who don't prescribe much, to perform clinical trials, when we can use the same money and pay it to practicing doctors who are prescribing our drugs. This leverages our value to them and us both." The idea to pay individual doctors a data fee to promote the use of Schering's earlier more hepatitis C therapy under the guise of a "clinical trial" as a way to increase sales was implemented by the oncology business unit along with ITG, including Greg Oakes, Bruce Wallace, and Gary Binder. Doctors were offered payments in exchange for "enrolling" patients into treatment with the earlier therapy and collection of "clinical trial data." To my knowledge, in-house counsel had little or no input into this strategy except for development of the contract template to establish facial legitimacy for this process. The collected data was of poor quality and of limited or no use and the business unit was aware of this outcome from the moment the scheme was introduced --- the purpose of the scheme was to drive sales by subjecting patients to treatment by the older therapy rather than collect useful

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data. Exhibits 550 and 551 show the implementation of Doliveaux's scheme that paid doctors to enroll patients on treatments of Intron-A and Temodar.

I declare under penalty of perjury that the foregoing is true and correct.

Charles M. Alcorn

Charles M. Alcorn

Dated: 01 Nov '06